

REMARKS

Claims 1-54 are pending in the present application. Claims 1, 19, 39, and 46 have been amended.

Reconsideration of the application is respectfully requested in view of the following responsive remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

In the Office Action of July 24, 2006 the following actions were taken:

- (1) The Examiner withdrew the 37 CFR 1.52(b)(4); 35 U.S.C. 112, second paragraph; and provisional double patenting rejections;
- (2) Claims 1-4, 6, 7, and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by an academic article entitled "Infrared Spectra of Aqueous Solutions. I. Metal Chelate Compounds of Amino Acids" published in the Journal of the American Chemical Society authored by Kazuo Nakamoto, Yuki Yoshi Morimoto, and Arthur E. Martell (JACS, 1961 83(22), 4528-4532) (hereinafter "Nakamoto");
- (3) Claims 1-4 and 12 were rejected under 35 U.S.C. § 102(b) as being anticipated by an academic article entitled "Metal Chelating Tendencies of Glutamic and Aspartic Acids" published in the Journal of Physical Chemistry authored by R. F. Lumb and A. E. Martell (J. Phys. Chem., 1953 57(7), 690-693) (hereinafter "Lumb");
- (4) Claims 1-8, 19-21, 29-31, 38-40, 44-46, 48-49, and 52-54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,504,055 (hereinafter "Hsu");
- (5) Claims 1-9, 11, 19, 22-24, 28-31, 38-40, 44-46, and 48-49 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,426,424 (hereinafter "Ashmead '424");
- (6) Claims 1-4, 15-24, 26-31, 34-40, 43-49, and 52-54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 4,725,427 (hereinafter "Ashmead '427");
- (7) Claims 19 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hsu in view of U.S. Pat. No. 6,299,896 (hereinafter "Cooper");
- (8) Claims 1, 13-14, 32-33, 41-42, and 50-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ashmead '427 in view of an academic article entitled "Production and Utilization of Amino Acids" published in Angewandte Chemie International

Edition authored by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter "Izumi");

It is respectfully submitted that the presently pending claims be allowed based on the remarks below.

Rejections Under 35 U.S.C. § 102

The Examiner has rejected claims 1-12, 15-24, 26-31, 34-40, 43-49, and 52-54 as being anticipated by several references. Before discussing the rejection, it is thought proper to briefly state what is required to sustain such a rejection. It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). In order to establish anticipation under 35 U.S.C. 102, all elements of the claim must be found in a single reference. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987). In particular, as pointed out by the court in *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1981), *cert denied*, 469 U.S. 851 (1984), "anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference." "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989). As the Examiner has rejected the four independent claims, two composition claims and two method claims, a discussion of these claims is provided.

Composition Claims 1 and 19

The Examiner has rejected claim 1 and/or 19 by several general amino acid chelate references; specifically, Lumb, Nakamoto, Hsu, Ashmead '424, and Ashmead '427. However, none of the references provide a hypoallergenic metal amino acid chelate composition as required by independent claims 1 and 19. The Applicant renews the arguments found in the prior Office Action response in regards to the Lumb and Nakamoto references in that they do not necessarily teach true chelates. However, regardless of these arguments, the Applicant would like to emphasize that the present invention requires a hypoallergenic metal amino acid chelate composition. The Applicant is not relying on the structure of the chelate compound *per se* to show its distinction over the prior art, but rather the composition as a whole (including impurities and other byproducts that are virtually

always present, etc.) that is different than the prior art. A chelate structure is not the same as a hypoallergenic composition that includes chelates. While the Applicant has thought that this distinction has been made clear, the pending claim set has been amended to remove any ambiguity as to this point of novelty in an effort to expedite the current prosecution.

Even if Lumb and Nakamoto formed chelates, the Lumb, Nakamoto, Hsu, Ashmead '424, and Ashmead '427 references do not teach a hypoallergenic chelate composition. In fact, the references never mention hypoallergenic at all. The Applicant has claimed a specific narrow class of chelate-containing compositions. The chelate-containing compositions must contain hypoallergenic components that are substantially free of allergens. The Examiner has restated that ““once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show the unobvious difference.”” See Office Action, page 12 (citing MPEP 2113). The Applicant contends that the composition is different than those found by the Examiner in Lumb, Nakamoto, Hsu, Ashmead '424, and Ashmead '427. The Applicant has already discussed that Lumb and Nakamoto are probably not true chelates as defined by Ashmead '427. Even so, none of these chelate-containing compositions claim to be hypoallergenic and nothing in the references suggest that these chelates are hypoallergenic. The current independent claims specifically require that the chelates be substantially free of allergens. The previous compositions cited by the Examiner make no such claim and take no such steps to eliminate allergens from their respective compositions. Therefore, it is the Applicant's contention that absent a specific process or method of manufacturing that eliminates allergens, the cited compositions inherently contain impurities and allergens. The present hypoallergenic requirement significantly changes the composition of the product. Under the present application, the present amino acid compositions are manufactured in such a manner that substantially eliminates allergens from the product. As such, the present compositions are chemically different than those disclosed in the prior art.

As the Examiner has not provided a single reference that contains each and every element of the present invention, the Applicant respectfully requests that the Examiner withdraw the current 102 rejections.

Method Claims 38 and 46

The Examiner has rejected claim 38 and 46 by several references; specifically, Hsu, Ashmead '424, and Ashmead '427. However, none of these references provide a method of

preparing or administering a hypoallergenic metal amino acid chelate composition. The Applicant renews the arguments previously made with respect to these references above. Additionally, independent claims 38 and 46 specifically require an affirmative hypoallergenic determination. Each independent method claim requires a determination of the individual metal and amino acid components for chelation in forming the composition. The present specification is specific in defining the terms hypoallergenic, allergy, and allergen, so that no ambiguity arises as to the Applicant's methods and compositions. Specifically,

“hypoallergenic” refers to compositions where care has been taken in formulation and/or production to ensure minimal instance of allergic reactions in a target subject or class of subjects. . .

“[a]llergy” refers to an acquired and abnormal immune response to a substance or moiety of a substance (allergen) that produces an altered bodily reaction. . .

“allergen” refers to a substance that causes manifestations of allergy, such as a protein or antigen.

See page 8, lines 12-29. Elaborating on this affirmative hypoallergenic determination, the specification states that “[d]etermining whether a composition or its source is hypoallergenic indicates that some type of evaluative step be performed.” See page 10, lines 21-28. None of the references provided by the Examiner refers to any such “evaluative step” as required by claims 38 and 46. Therefore, the Examiner has not provided a reference that requires every element of the method claims.

Furthermore, the Applicant wishes to remind the Examiner that the product by process inquiry for composition patentability has no relation to the inquiry for the patentability of a method. The product is not required to be novel for patentability of the method. The method is viewed independent of the product. With this in mind, the Examiner has not provided a reference that provides an affirmative step of hypoallergenic determination as part of the method in producing a metal amino acid chelate. The Examiner “notes the affirmative hypoallergenic determination steps” of the present claim set; nevertheless, the Examiner “respectfully submits that the methods are taught by the prior art for the reasons of record and those stated above.” However, there are no “reasons of record”

or any other reasons in the present office action that explain how the Examiner is rejecting the method claims. The Examiner has stated several times that ““patentability of a product does not depend on its method of production.”” This point has been stressed through multiple office actions, but does not apply to the method claims; composition novelty is an independent inquiry. The Applicant wishes to remind the Examiner that, in regards to the method claims, the sole inquiry is: have the methods of the present invention previously been disclosed in a single reference or combination of references? The clear answer to that inquiry is no. None of the references provide an affirmative evaluative step.

Furthermore, the Applicant wishes to point out the additional requirements of independent claim 48, which requires “identifying a subject susceptible to a type of allergic reaction” and “formulating a metal amino acid chelate” by selecting “amino acid source[s]” and “metal source[s] determined to be hypoallergenic with respect to the type of allergic reaction. . . .” See claim 48. Where are these steps taught in the prior art?

Since the Examiner has not provided any single reference that provides each and every element of the present claims, the Applicant respectfully requests that current 102 rejections be withdrawn. As the Applicant has explained the novelty of the independent method claims over the prior art, the Applicant respectfully requests that the Examiner withdraw the 102 rejections for the corresponding dependent claims as well.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 1, 13-14, 19, 25, 32-33, 41-42, and 50-51 under 35 U.S.C. 103(a) as being unpatentable over several references.

Applicant does not deem it necessary to recited the entire case law standard required in order to establish a *prima facie* case of obviousness. However, Applicant, would like to briefly remind the Examiner of the required three criteria for a *prima facie* case of obviousness, namely that the asserted references as modified or combined must: 1) teach or suggest each and every element of the claimed invention; 2) provide sufficient motivation for the modification or combination asserted; and 3) provide a sufficient likelihood of successfully making the modification or combination.

Emphasis on the two independent compositional claims is provided herein, as the Applicant asserts that these claims are all patentably distinct over the prior art. Specifically, the Examiner has rejected claims 1, 13-14, 19, 25, 32-33, 41-42, and 50-51 as being obvious in view of various combinations of Hsu, Cooper, Ashmead ‘427, and Izumi. Specifically, as

the Examiner has rejected two independent claims, 1 and 19, a discussion of these claims is provided.

The Examiner has combined two references, specifically Ashmead '427 and Izumi, to reject claims 1, 13-14, 32-33, 41-42, and 50-51. The Examiner has combined these references since Ashmead '427 does not teach "1) a method other than protein hydrolysis; 2) protein hydrolysis and wherein the protein used in the hydrolysis is hypoallergenic." See Office Action, page 11. The Examiner then states that Izumi teaches multiple methods including "enzymatic, fermentation, extraction (protein hydrolysis) and synthetic methods." See Office Action, page 11. However, as previously argued, where does Izumi teach the hypoallergenic element required by all four independent claims? All four independent claims require a hypoallergenic component. The two compositional claims require that the hypoallergenic chelate be substantially free of allergens such that the chelate composition does not cause a discernable adverse allergic reaction in a subject. The two independent method claims require that specific hypoallergenic determinations are made of both the metal and amino acid and that the final product be a hypoallergenic chelate. Izumi never mentions that its amino acid methods are hypoallergenic or that it produces a hypoallergenic product. Additionally, as previously discussed, Ashmead '427 also does not teach a hypoallergenic composition. Therefore, the combination of these two references would not successfully provide a hypoallergenic metal amino acid chelate composition as required by composition claim 1. In fact, the Examiner has not shown any such language in any reference in the current office action. The remaining rejected claims are dependent claims. The Applicant contends that every dependent claim also contains the hypoallergenic requirement through dependency. As such, the Applicant submits that these claims are also novel in view of the prior art.

As the Examiner has not provided a combination of references that teach or suggest every element of the claimed invention and as the current combination of references would have no likelihood of success in producing the Applicant's invention, the Applicant respectfully requests that the corresponding 103 rejections be withdrawn.

The Examiner has combined two references, specifically Hsu and Cooper, to reject claims 19 and 25. As previously discussed, Hsu does not teach a hypoallergenic chelate composition. The Examiner has also identified this limitation, stating "Hsu et al. do not expressly disclose a composition wherein the formulation additive is a hypoallergenic flow control agent . . ." See Office Action, page 9. The Examiner then relies on Cooper as

teaching the use of “the lubricant stearic acid.” See Office Action, page 10. But where does Cooper teach a hypoallergenic flow control agent as identified by the Examiner? Cooper never states that the stearic acid is hypoallergenic or that any other materials or products are hypoallergenic. The Examiner has not shown any such language in any reference in the current office action, nor has the Examiner has provided a combination of references that teach or suggest every element of the claimed invention. As such, the combination of these two references would not successfully provide a hypoallergenic chelate composition. Therefore, the Applicant respectfully requests that the corresponding 103 rejection be withdrawn.

Conclusion

Because no reference has been shown that teaches a hypoallergenic chelate composition or a method using an affirmative hypoallergenic evaluative step, the Applicant respectfully asserts the Examiner has not satisfied the requirement for establishing a case of *prima facie* anticipation or of *prima facie* obviousness. Therefore, it is believed the present claim set should be allowable. Reconsideration is respectfully requested.

In view of the foregoing, the Applicant believes that claims 1-54 present allowable subject matter and allowance is respectfully requested. If any impediment to the entry of the present amendment and reconsideration of the claims in view thereof remains which could be removed during a telephone interview, the Examiner is invited to telephone Mr. Gary Oakeson of this office, or in his absence, M. Wayne Western, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to
Deposit Account No. 20-0100.

Dated this 24th day of October, 2006.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gary P. Oakeson", written over a horizontal line.

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